



Food and Drug Administration
Rockville MD 20857

DEC 11 1990

Re: Exosurf Neonatal
Docket No. 90E-0343

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,312,860, filed by Burroughs Wellcome Co. under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Exosurf Neonatal, the human drug product claimed by the patent.

The total length of the review period for Exosurf Neonatal is 1,891 days. Of this time, 1,723 days occurred during the testing phase and 168 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 31, 1985.

FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was May 31, 1985.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 16, 1990.

FDA has verified the applicant's claim that the new drug application (NDA 20-044) was filed on February 16, 1990.

3. The date the application was approved: August 2, 1990.

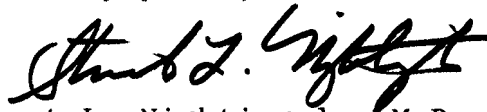
FDA has verified the applicant's claim that NDA 20-044 was approved on August 2, 1990.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Stuart L. Nightingale". The signature is stylized with a large, looped initial "S" and a long, sweeping underline.

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Lawrence A. Nielsen
Head, Patent Department
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709